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Triple Threat: EMA Endorses Three First-Time Biosimilars

CHMP Backs Rivals To Eylea/Aflibercept, Tysabri/Natalizumab And RoActemra/Tocilizumab

by David Wallace

At an eventful European Medicines Agency committee meeting in July, three biosimilars from Biocon, Sandoz and Fresenius Kabi have become the first for each respective molecule – aflibercept, natalizumab and tocilizumab – to gain the endorsement of the CHMP.

After several months' wait for new biosimilar molecules to be endorsed by the European Medicines Agency, three have come along at once, with the agency's Committee for Medicinal Products for Human Use today issuing positive opinions for rivals to Eylea (aflibercept), Tysabri (natalizumab) And RoActemra (tocilizumab).

While CHMP positive opinions do not constitute formal approval, the European Commission typically acts within 67 days to convert them into pan-European marketing authorizations, setting the stage for these biosimilars to challenge three fresh brands as and when they come to market.

Yesafili: Biocon's Eylea (Aflibercept) Biosimilar

Yesafili (aflibercept), *Biocon Biologics*' rival to Eylea, was granted a positive opinion by the CHMP.

The positive opinion covers Yesafili for treating neovascular (wet) age-related macular degeneration, visual impairment due to macular oedema secondary to retinal vein occlusion, visual impairment

Biocon Biologics Integrates Viatris

due to diabetic macular edema and visual impairment due to myopic choroidal neovascularization.

The biosimilar was filed by Viatris, which recently sold its biosimilars business to former partner Biocon (*see sidebar*), with the deal including Biocon picking up rights to the aflibercept candidate.

Yesafili has been endorsed by the CHMP as a 40mg/ml solution for injection that must only be administered by a qualified physician experienced in administering intravitreal injections.

Business As It Introduces Adalimumab

By David Wallace

13 Jul 2023
In a busy couple of weeks for Biocon's biosimilars unit, the firm has completed the "first wave" of integration for the business it acquired from Viatris, while also launching its US adalimumab biosimilar amid heavy competition.

Read the full article here

"Data show that Yesafili has comparable quality, safety and efficacy to Eylea," the CHMP stated.

Tyruko: Sandoz And Polpharma Biologics' Tysabri (Natalizumab) Rival

Tyruko (natalizumab), a biosimilar to Tysabri developed in partnership by *Polpharma Biologics* and *Sandoz*, was also issued a positive opinion by the CHMP.

The multiple sclerosis treatment – which will be available as 300mg concentrate for solution for infusion – has been highlighted by Sandoz in recent months as one of its most significant near-term biosimilar assets, especially given that no other rivals to Tysabri are on the horizon.

Referring to one of Sandoz's other biosimilars, Omnitrope (somatropin), the company's global head for biosimilars Peter Stenico recently told *Generics Bulletin* that natalizumab had the potential to "evolve into that kind of story, where we are the only one with 17 years on the market."

Biosimilars Loom Large As Sandoz Sets Stage For Spinoff

By David Wallace

19 Jun 2023
At a pair of capital markets days in New York and London, Sandoz has set out expectations for its post-spinoff future – with biosimilars featuring heavily in the company's growth plans.

Read the full article here

Due to the complexity of the product, "nobody that we know of is really in development," Stenico outlined. "We will hopefully be the only one for a very long time. And we will shape that

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market." (Also see "*'What's Really Important Is, What Are We Doing Next?': Sandoz On Biosimilar Ambitions*" - Generics Bulletin, 9 Jun, 2023.)

"Data show that Tyruko has comparable quality, safety and efficacy to Tysabri," the CHMP confirmed.

Tyenne: Fresenius Kabi's RoActemra (Tocilizumab) Challenger

Tyenne, a biosimilar version of RoActemra (tocilizumab) filed by *Fresenius Kabi*, was the third biosimilar to receive a positive opinion from the CHMP.

The positive opinion covers Tyenne for the treatment of rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis, CAR-T cell-induced severe or life-threatening CRS and COVID-19.

Tyenne will be available as a 20mg/ml concentrate for solution for infusion and a 162mg/ml solution for injection. "Data show that Tyenne has comparable quality, safety and efficacy to RoActemra," the CHMP said.

Fresenius said the positive opinion represented an "important milestone in the company's Vision 2026 growth strategy."

"The positive opinion covers both subcutaneous (pre-filled syringe and autoinjector) and intravenous administrations," the firm pointed out, "which offer a comprehensive, alternative treatment solution for patients treated with tocilizumab."

Pierluigi Antonelli, CEO of Fresenius Kabi, said the CHMP endorsement was "a major milestone on our pathway towards leadership in the biosimilar sector," insisting that "our tocilizumab candidate will make a difference for patients with autoimmune diseases and will benefit health systems in the EU."

'You Have To Play On A Pretty Broad Part Of The Piano': Fresenius Kabi On Biosimilar Commitment

By Dean Rudge

20 Jul 2023

During a broad and wide-ranging interview, taking place in the aftermath of Fresenius Kabi's entry into the US adalimumab biosimilar market, president of the firm's Biopharma business, Michael Schönhofen, talks about Kabi's ambitions in the space, and how it is positioned to be a long-term player.

Read the full article here

Meanwhile, Fresenius Kabi biopharma president Michael Schönhofen said the company was "very proud to be at the forefront of providing an alternative, affordable, and high-quality

tocilizumab treatment option to patients living with autoimmune diseases."

"With our expanding biosimilars portfolio for immunology and oncology related conditions, we will deliver on our promise to provide access to biosimilars to more patients and healthcare providers around the world," he attested. "Our Vision 2026 growth commitment to biopharma and improving the quality of patients' lives establishes us as a trustworthy partner to alleviate the burden on healthcare systems globally."

In an exclusive interview, Schönhofen recently spoke to *Generics Bulletin* in detail about Fresenius Kabi's biosimilars strategy (*see sidebar*).

Accord's Degarelix Generic Also Gains Positive Opinion

As well as the three biosimilars, another CHMP positive opinion for an off-patent medicine came in the form of the committee's endorsement of Accord's generic rival to Firmagon (degarelix) for the treatment of hormone dependent prostate cancer.

Degarelix Accord will be available as an 80mg and 120mg powder and solvent for solution for injection.

"Studies have demonstrated the satisfactory quality of Degarelix Accord, and its bioequivalence to the reference product Firmagon," the CHMP stated.

It noted that "a bioequivalence study versus the reference product Firmagon was not required because of the qualitative and quantitative compositions and the nature and behaviour of the products."